K052296
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510(k) SUMMARY

SEP 0 2 2005

SUBMITTER INFORMATION

A. Company Name: Spectranetics Corporation, Inc.

B. Company Address: 96 Talamine Court
Colorado Springs, Colorado 80907

C. Company Phone: 719-633-8333 / 1-800-633-0960

D. Company Facsimile: 719 442 2248

E. Contact Person: Adrian Elfe
Vice President
Quality Assurance & Regulatory Affairs Compliance

DEVICE IDENTIFICATION

A. Device Trade Name: CLiRpath Turbo Excimer Laser Catheter

B. Device Common Name: Laser Catheter

C. Classification Name: Catheter, Peripheral, Atherectomy

D. Device Class: Class II (per 21 CFR 870.4875)

E. Device Code: MCW

IDENTIFICATION OF PREDICATE DEVICES

Spectranetics CLiRpath excimer laser catheters for peripheral use, cleared to market under 510(k) K040067, serve as predicate to the line of CLiRpath excimer laser catheters with Continuous-On capability. The 2.5 mm CLiRpath Turbo excimer laser catheter, cleared under 510(k) K043465, likewise serves as a predicate.

DEVICE DESCRIPTION

Spectranetics' CLiRpath excimer laser atherectomy catheters, including CLiRpath Turbo models, consist of a bundle of optical fibers, encased within medical grade tubing. The optical fibers conduct ultraviolet laser light (excimer laser light at 308 nm) from a source to the tip of the catheter. The catheter is inserted into a patient's vasculature along the length of a previously inserted medical guidewire, allowing the attending physician to deliver laser energy targeted to a lesion (blockage) in the blood vessel. CLiRpath laser catheters are provided in models designed for both "over-the-wire" and rapid exchange interventional techniques. Laser energy impinged on a blockage ablates, or debulks, the lesion material re-establishing blood flow within the vessel, and permitting placement of devices used in vascular interventions.

Spectranetics brand CLiRpath Turbo laser catheters will be supplied in addtional tip diameters between 0.9 and 2.3 mm, appropriate for interventional use in the peripheral vasculature of the leg.

INTENDED USE

For use in the endovascular treatment of symptomatic infrainguinal lower extremity vascular disease where total obstructions can not be crossed with standard guide wires.

COMPARISON TO PREDICATE DEVICES

CLiRpath Turbo catheters for peripheral use are substantially equivalent in form, fit, and function to other Spectranetics CLiRpath laser catheters, including the 2.5 mm Turbo catheter, which have received market clearance under section 510(k) rules. CLiRpath Turbo catheters form an addition to the CLiRpath product line, providing the medical community with more control over the duration of treatment. Prior models of CLiRpath catheters, excluding the 2.5 mm Turbo model, delivered ablating laser energy for up to 10 seconds, when the activating footswitch was depressed, before electronic controls stopped the system for at least 5 seconds. Only the 2.5 mm Turbo predicate was provided with CLiRpath Turbo capability. Thus successful treatment often required several trains of 10-second laser pulses. The CLiRpath Turbo feature of the new CLiRpath catheter models allows interventions to proceed without the delay in treatment entailed due to a programmed on-off sequence, using catheter tip dimensions over a range from 0.9 mm to 2.3 mm.

CLiRpath Turbo laser products are fiber optic catheters with working lengths to choose from between 120 cm and 150 cm. Tip diameters range from 0.9 mm to 2.3 mm. The catheters deliver excimer laser energy at 308 nm to an occlusion within a patient's targeted peripheral artery. Delivered energy disrupts occlusive material, such as arterial plaque, and permits its removal via the patient's reticuloendothelial system. The pathway opened by either the predicate device or the Turbo catheter, facilitates subsequent placement of other devices and interventions, and re-establishes blood flow within the diseased vessel.

BIOCOMPATIBILITY, STERILIZATION, PACKAGING, AND BENCH TESTING

CLiRpath Turbo excimer laser catheters are built from the same components and materials of construction as other, already-marketed, Spectranetics products. Therefore, biocompatibility of both component materials and the finished CLiRpath Turbo catheters have been previously confirmed in accord with the ISO 10993 series of standards, Biological Evaluation of Medical Devices. Spectranetics conducts and maintains valid ethylene oxide sterilization processes in accord with ISO 11135, Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization. Package integrity is initially validated, and, in addition, visually verified for 100% of Spectranetics devices prior to transfer to finished goods inventory.

Device integrity and functionality were qualified and/or validated using samples produced under routine manufacturing conditions. All CLiRpath Turbo excimer laser catheter models meet or exceed both Spectranetics in-house requirements, and requirements listed in ISO 10555-1, Sterile, Single-use Intravascular Catheters – Part 1: General Requirements.

CONCLUSION

The above statements establish substantial equivalence between the CLiRpath predicate devices, including 2.5 mm Turbo model, and the full line of CLiRpath Turbo excimer laser catheters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Spectranetics Corporation
c/o Mr. Neil Burris
Clinical Data Services
96 Talamine Court
Colorado Springs, CO 80907

SEP 18 2013

Re: K052296
Trade/Device Name: CLiRpath Turbo Excimer Laser Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: August 22, 2005
Received: August 23, 2005

Dear Mr. Burris:

This letter corrects our substantially equivalent letter of September 2, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K052296

7. Statement of Indication for Use

Device Name: Spectranetics CLiRpath Turbo™ Excimer Laser Catheter

Indications for Use

For use in the endovascular treatment of symptomatic infrainguinal lower extremity vascular disease where total obstructions can not be crossed with standard guide wires.

Prescription Use XXXX (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K052296